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Safety of Nimesulide medicine

3165. SHRI GHULAM NABI AZAD : Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government are aware regarding the controversy about the safety of Nimesulide medicine which has confused many patients and some doctors;

(b) if so, whether it has served a purpose in the sense that it focused on the complete absence of an Adverse Drug Reaction (ADR) mechanism in the country;

(c) whether Government are also aware that mechanisms are in place in many countries to trade down a drugs' efficacy and side effects over the years, but in India a drug that hits the market stays there; and

(d) if so, what steps Government are taking to stop such drugs having dangerous side effects?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA) : (a) Yes, Sir.

(b) to (d) A comprehensive Pharmacovigilance Programme to capture Adverse Drug Reaction (ADR) data by involving large number of Medical Institutions throughout the country has been framed under World Bank assisted capacity building project for drugs. A specific adverse drug reaction reporting proforma has already been provided on the website-www.cdsco.nic.in. Presently three adverse drug reaction-monitoring centres are functioning at KEM Hospital Mumbai, AIIMS New Delhi; and K.G. Medical College, Lucknow.

Review of drugs reported to be harmful/withdrawn in some countries is undertaken on a continuous basis by an expert committee of Drug Technical Advisory Board (DTAB). So far 74 categories of drugs and formulation have been prohibited. It has also been made mandatory for drug marketing firms to conduct Post Marketing Surveillance (PMS) studies for new drugs.